Creating arteriovenous fistula using an automatic anastomotic device

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We describe the use of the Cardica C-Port xA Distal Anastomosis System for performing an automated, arteriovenous fistula in patients on hemodialysis with end stage renal failure. (J Vasc Surg 2011;53:531-3.)

One of the main problems of vascular access for hemodialysis has been the patency of vascular anastomoses, which is most often disturbed due to intimal hyperplasia. A variety of reports have described the advantages provided by mechanical devices over the conventional needle-and-suture technique for the construction of an arteriovenous fistula, although none of them has been widely accepted.[1] The C-Port System (Cardica, Inc, Redwood City, Calif) integrates in one tool all functions necessary to enable rapid, consistent, sutureless, automated anastomoses, suitable for small arteries. This device has been mainly developed for creating fast venous or arterial graft-to-coronary artery anastomosis in off-pump bypass surgery,[2] although it has been used as well for anastomoses in other anatomic locations such as carotid to middle cerebral artery bypass,[3] and bypass of the renal artery for aneurysm exclusion.[4] We used the Cardica C-Port system in 5 patients with renal failure to perform a radiocephalic fistula in the wrist, rather than the standard technique of a handmade anastomosis between the radial artery and cephalic vein.

METHOD

The Cardica C-Port Anastomosis System is a single-patient use device. It was designed to create a reliable and consistent end-to-side anastomosis between a conduit and a small vessel. It consists of a handle bearing the actuation button, a cartridge, and an anvil. The anvil is 1 mm in diameter with an arteriotomy knife incorporated. The cartridge consists of two arms where the graft is positioned, four spikes to attach the graft, and contains eight metallic clips. This device has the Food & Drug Administration's approval for use in the United States (Fig 1). Cephalic vein and radial artery are isolated and prepared for an end-to-side anastomosis. The arterial and venous segment should be long enough in order for the anastomosis to show no tension or twisting and the distal-end needs to be free of side branches, clips, sutures, or connective tissue over a 15 mm length. Patency of the proximal cephalic vein is verified by injection of warm saline solution (37°C). A stab hole with an 11 knife, sufficient to allow blood to flow, and insertion of a 1 mm vessel probe in the radial artery is performed; consequently, the cephalic vein is inserted between the two cartridge arms and attached by the four small spikes. The anvil of the C-Port is inserted into the incision of the artery. When placed correctly, the deployment of the anastomotic device begins by slowly depressing the trigger. As a result, the cartridge closes on the target vessel and the connection between the vein graft and the artery is rapidly performed without the need for temporary occlusion of the target vessel. A compliant, angled, end-to-side anastomosis is performed by automatically placing eight individual clips and, at the same time, an arteriotomy knife located inside the anvil automatically creates an arteriotomy approximately 4 mm in length with the push of a button. Upon completion, the trigger is released and the anvil is removed from the target vessel. A Prolene 6-0 or 7-0 Π suture is finally used to close the incision after completion of the anastomosis with a figure of eight (Fig 2).

Arteriovenous fistula creation was successful in all patients. Intraoperative and postoperative Doppler ultrasound scans revealed a patent anastomosis, and in 2-months' follow-up, Doppler ultrasound showed perfect function of the fistula in all patients. The mean cephalic vein diameter increased from 2.3 mm to 6.3 mm, allowing cannulation of the vessel as a "mature fistula" in all patients.

DISCUSSION

The C-Port System allows rapid automated distal anastomoses by integrating all the functions necessary for completing an anastomosis.

The use of the C-Port system encompasses the following advantages: it can be used for diverse types of fistulas, such as autogenous wrist ulno-basilic, autogenous wrist radio-basilic transposition, radio-cephalic, brachio-basilic, and brachio-cephalic. The system is suitable for vessels (artery or vein) with an internal diameter as small as 1 mm. Performing an anastomosis with such small vessels is often

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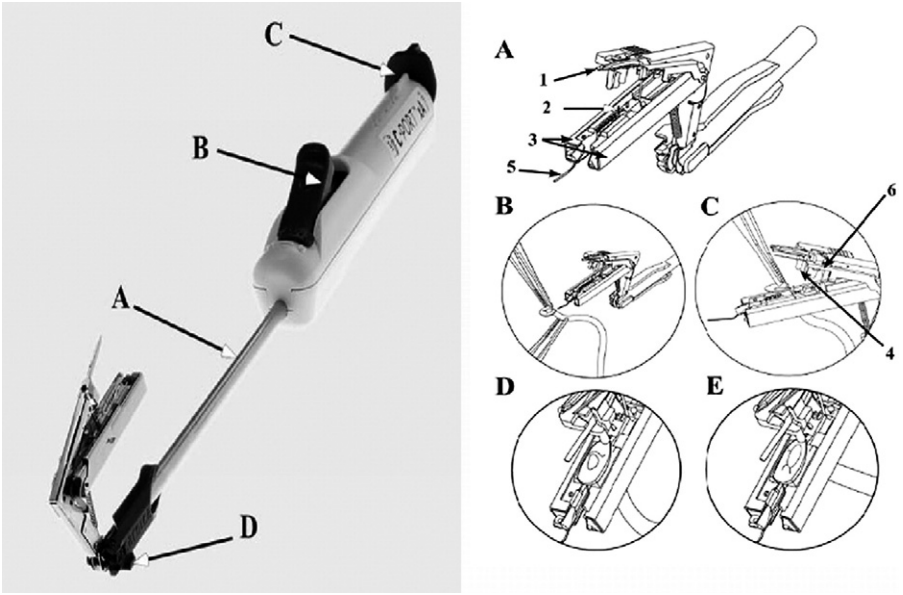

Fig 1. The C-Port system: image on the left shows the parts of the C-Port system, **(A)** shaft, **(B)** trigger, **(C)** activation knob, and **(D)** head of the device (can be rotated in the plane of the shaft). The image on the right is a schematic depicting the loading technique. Panels **(A)** and **(C)** show the anvil *(1)*, heel clip *(2)*, cartridges *(3)*, the piercer *(4)*, the shield *(5)*, and the clamp *(6)*. In panel **(A)** the distal end of the graft that will be located at the heel of the anastomosis is shown. An incision long enough to allow the distal end of the graft to cover the entire cartridge surface area is created. The shield *(5)* is flipped outward so that the tip of the shield is facing away from the cartridge. The piercer *(4)* is rotated upward until it stops. This action will expose the tip of the heel clip. In panels **(B)** and **(C)**, forceps are used to advance the graft, incised edge first, between the cartridge arms *(3)*. This action can be facilitated by using a second forceps to grasp the graft on the underside of the cartridge while sliding in between the arms. With the aid of the forceps, the two flaps of the graft are grasped at the base of the incision and held above the tine of the heel clip *(2)*. In panels **(D)** and **(E)**, the conduit is held in position as the left graft clamp is lowered with the piercer *(4)* until it has fully pierced the conduit on the heel clip *(2)*. Once the graft is aligned and the graft tissue completely covers the full length of both loading platforms, the left graft clamps are lifted to the upper-most position and the piercer is slid forward to detach. The two graft clamps are then lowered *(6)*. The C-Port system is ready for the target vessel anastomosis.

challenging. This new device's capability might potentially have the biggest impact on these small vessels, as small vessel diameter is an important factor for technical difficulty. It completes an anastomosis rapidly and safely, producing consistent and reproducible anastomosis. The time of harvesting the target vessels is the same as for the conventional arteriovenous fistula, but the completion of the anastomosis itself can be approximately 2 minutes. Furthermore, it allows mechanically governed repeatability and reduced procedural complexity, and the opportunity to work with grafts of various diameters and wall thicknesses of less than 1.4 mm. Finally, it minimizes scarring and potential occlusion of the anastomosis by achieving nearly complete alignment of the natural blood lining surfaces of the artery and vein. Additionally, the metallic clips are subintimally placed, thus producing less endothelium destruction and having minimal contact with the bloodstream, reducing thrombogenic stimulus. The atraumatic nature of this procedure avoids injury of the intima, activation of platelets and growth factors, and migration of vascular smooth muscle cells from the media to the intima, a process mainly initiated by injuries like handling with forceps and sutures. As such, we could thereby presume that stenosis and thrombosis rates, along with inflammation and intimal hyperplasia, are possibly kept to a minimum. Some of the device's disadvantages are the limitations as to the size of the target and conduit vessels and the inability to be used on highly calcified or diseased vessels, as with conventional surgical anastomoses. It is indisputable that the cost of this device is much higher than the plain needle and suture technique if we had to compare the two. Yet, the fistulae created with hand sewn anastomoses often suffer from many failures (about 20% during the first month), and in the group of patients above 70 years old, even more often (40% patency after 1 year).[5] Readmissions and repeated procedures also involve a high cost. If by using this device, thrombosis, stenosis, and malfunction of the fistula are minimized and patency rates are increased, then we can say that in the long term this could be a cost-effective device. The C-Port system has been developed and tested in coronary artery bypass surgery for rapid distal coronary artery anastomoses. A multicenter study by Matschke et al[2] showed an overall patency of 92.1% at 1 year follow-up in coronary anastomoses by means of angiography.

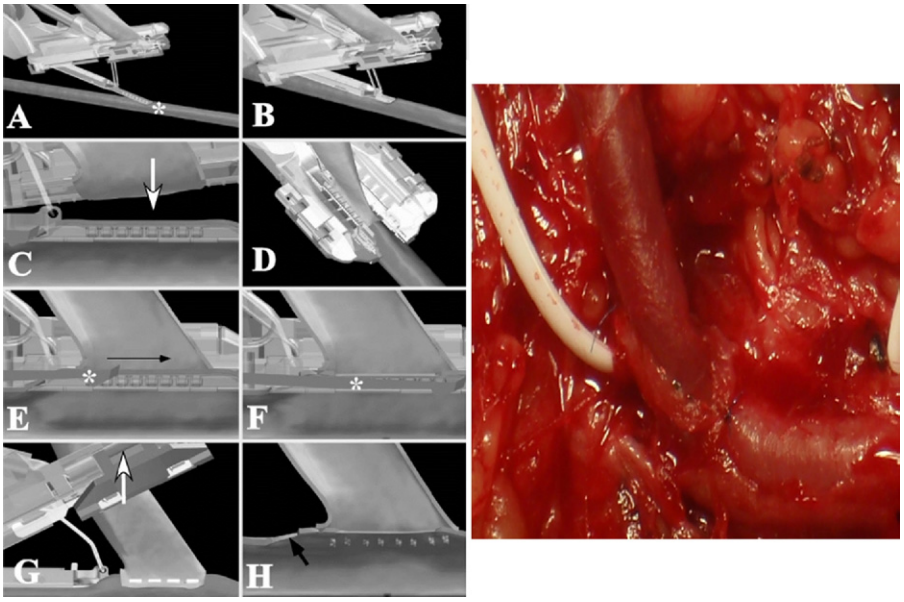

Fig 2. The image on the left shows computer images of the C-Port system deployment sequence. **A,** A small opening (1 mm) in the target vessel is created *(asterisk)*. **B,** The anvil is inserted into target vessel. The graft is preloaded onto the cartridge. **C,** The deployment trigger is actuated and the cartridge is closed *(arrow)*. **D,** Top view of the closed cartridge with staples being deployed. The staples are deployed through the graft and target vessel and form against anvil surfaces. Panels **(E)** and **(F)** simultaneously show an arteriotomy knife *(asterisk)* inside the anvil that creates an opening in the target vessel from the inside out. **G,** The actuation trigger is released and the cartridge opens *(arrow)*. **H,** The anvil is removed from target vessel, and the anvil insertion hole is closed with a separate stitch *(arrow)*. The image on the right shows a surgical image of the radio-cephalic fistula after completion with the Cardica C-Port System.

However, in order to evaluate and compare the use of this novel device with the handmade anastomosis for arteriovenous fistulae concerning primary patency, thrombosis and stenosis rates, incidence of hand ischemia, delayed maturation and dysfunction, and cost-effectiveness, large randomized studies are needed.

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